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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,518	07/01/2005	Stefan Sperl	2923-671	1246
6449	7590 09/12/2006	EXAMINER		
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			KUMAR, SHAILENDRA	
SUITE 800	1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005		ART UNIT	PAPER NUMBER
WASHINGT			1621	
			DATE MAILED: 09/12/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
Office Action Commence	10/517,518	SPERL, STEFAN			
Office Action Summary	Examiner	Art Unit			
	SHAILENDRA KUMAR	1621			
<ul> <li>The MAILING DATE of this communication app</li> <li>Period for Reply</li> </ul>	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  B6(a). In no event, however, may a reply be time  rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) ☐ Responsive to communication(s) filed on 7/1/0.  2a) ☐ This action is FINAL. 2b) ☐ This  3) ☐ Since this application is in condition for allowar	action is non-final.	osecution as to the merits is			
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims					
<ul> <li>4) ☐ Claim(s) 1-16 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdraw</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1-16 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or</li> </ul>	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10)⊠ The drawing(s) filed on <u>13 December 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correcting The oath or declaration is objected to by the Ex	•				
Priority under 35 U.S.C. § 119		, , , , , , , , , , , , , , , , , , , ,			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicati ity documents have been receive (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)					
1) X Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P	ote			
3) MInformation Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/15/05, 9/16/05.	6) Other:	aton Application			

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#### **DETAILED ACTION**

Claims 1-16 are pending in this application.

## **Priority**

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 5/15/05 and 9/16/05(Duplicate) are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

### **Drawings**

3. The drawings were received on 12/13/04. These drawings are acceptable.

## Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 1-12 provides for the use of compounds of formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

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35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of WO 92/08709 and WO 00/17158.

Instant claims are directed to Guanidino phenylalanine compounds and their use as urokinase inhibitors.

WO'709 teaches structurally similar compounds and composition as claimed herein. Note, page 6, wherein R1 can be guanidine as well as amidine, R2 can be OH or OR, R4 can be substituted or unsubstituted phenyl and R3 can be H or alkyl. The difference between the reference and herein claimed subject matter is that the

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reference compounds are used for blood coagulation as against urokinase inhibition method in herein.

WO'158 is cited to show that the structurally similar compounds as claimed herein can be used as urokinase inhibitors, see pages 2-7.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the compounds of WO'709 in the method of inhibition of urokinase, as taught by WO'158, because the latter reference is expressly teaching that structurally similar compounds as claimed can be used in the inhibition of urokinase. Note the equivalence of guanidine and amidino group taught by WO'709.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571)272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHAILENDRA - KUMAR Primary Examiner Art Unit 1621

S.Kumar 9/5/06